

TÜV NORD CERT GmbH, Am TÜV 1, 45307 Essen, Germany

German Special Alloys GmbH
Carl-Friedrich-Benz-Straße 1b
47877 Willich
Germany

TÜV NORD CERT GmbH

Am TÜV 1
45307 Essen
Germany

Phone: +49 201 825 2236

medical@tuev-nord.de
tuev-nord-cert.com/en

TÜV®

Reference

No.: 44 235 151578

Contact

medical@tuev-nord.de

Direct Dial

Tel.: +49 201 825 2236

Date

16 September 2026

Notified Body Confirmation Letter

Reference: EC-Certificate acc. 93/42/EEC Annex V, No.: 44 235 151578

8003066434

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that TÜV NORD CERT GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0044 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

German Special Alloys GmbH
Carl-Friedrich-Benz-Straße 1b
47877 Willich
Germany
SRN: DE-MF-000005088

Headquarters
TÜV NORD CERT GmbH

Am TÜV 1
45307 Essen, Germany

Phone: +49 201 825-0
Fax: +49 201 825-2517
info.tncert@tuev-nord.de
tuev-nord-cert.com/en

Director
Dipl.-Ing. Wolfgang Wiepütz
Dipl.-Oec. Sandra Gerhartz

Registration Office
Amtsgericht Essen
HRB 9976
VAT ID No.: DE 811389923
Tax No.: 111/5706/2193

Deutsche Bank AG, Essen
BIC (SWIFT-Code): DEUTDE33XXX
IBAN-Code: DE26 3607 0050 0607 8950 00



The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

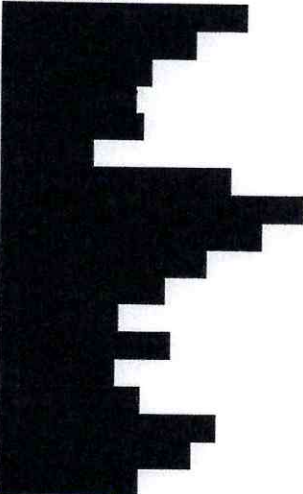
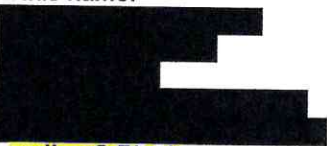
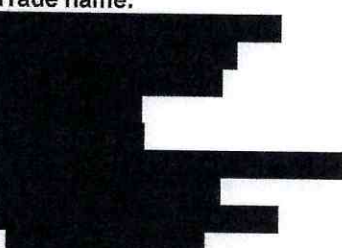
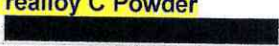
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i. V. Kevin Mühlenberg
Head of Project Management
Medical Devices International
TÜV NORD CERT GmbH
Notified Body for Medical Devices

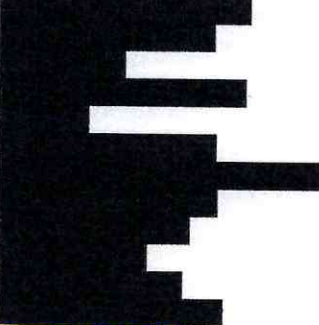
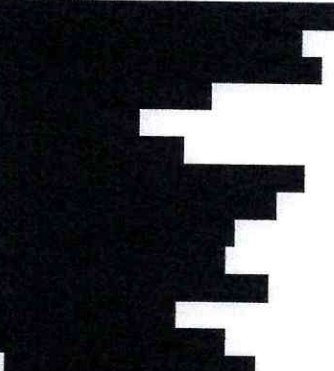
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i. V. Dr. Benjamin Hoy
TIC Manager MDR
Medical Devices International
TÜV NORD CERT GmbH
Notified Body for Medical Devices

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
GS-Alloy 1010 CB ++EGSAALMEKACOB SGZBD; ++EGSAALMEKACOBSDRAL Trade name:  - realloy C 	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1010 CB Blank ++EGSAALMEKACOB SFB9S Trade name:  - realloy C Blank	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1010 CB Powder ++EGSAALMEKACOB SPUBW Trade name:  - realloy C Powder 	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1010 CB Softblank ++EGSAALMEKACOB SSBZ Trade name: 	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578

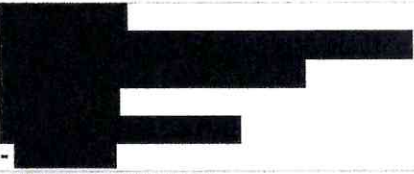
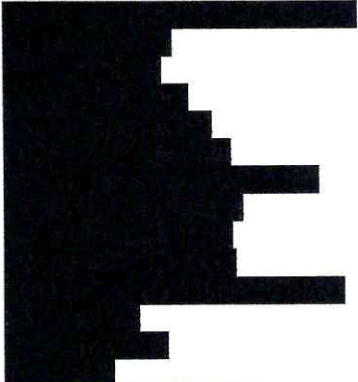
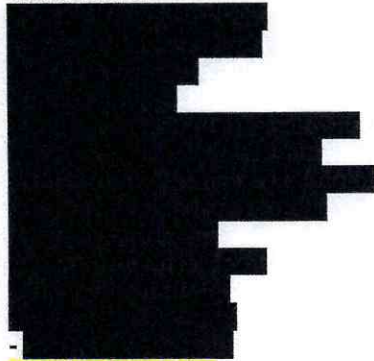
Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
[REDACTED] - realloy C Softblank GS-Alloy 1010 CB Softblank R ++EGSAALMEKACOBSSBAZ Trade name: [REDACTED] - realloy C Softblank R - [REDACTED]	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1020 CV ++EGSAALMEKACOB SGZBD; ++EGSAALMEKACOBSDRAL Trade name: [REDACTED] - realloy CH - [REDACTED]	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1020 CV Blank ++EGSAALMEKACOB SFB9S Trade name: [REDACTED] - realloy CH Blank [REDACTED] - [REDACTED]	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1020 CV Powder ++EGSAALMEKACOBSPUBW Trade name: [REDACTED] - [REDACTED]			

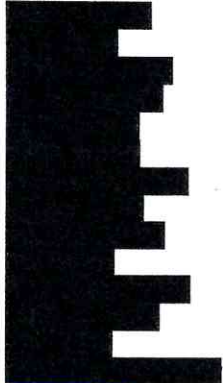
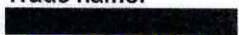
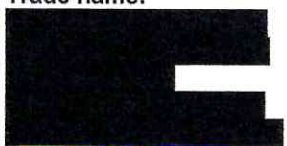
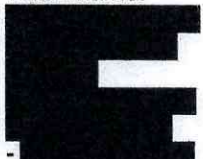
Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
 - realloy CH Powder - realloy CH RPD  -			
GS-Alloy 1023 Classic ++EGSAALMEKACOBGZBD; ++EGSAALMEKACOBSDRAL Trade name:  - realloy Classic  -	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1023 Classic Blank ++EGSAALMEKACOBFB9S Trade name:  - realloy Classic Blank	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1023 Classic Powder ++EGSAALMEKACOBSPUBW Trade name:  -	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
- realloy Classic Powder [REDACTED]			
GS-Alloy 1023 Classic Softblank ++EGSAALMEKACOBSSBAZ Trade name: [REDACTED] - realloy Classic Softblank [REDACTED]	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1023 Classic Softblank R ++EGSAALMEKACOBSSBAZ Trade name: [REDACTED] - realloy Classic Softblank R	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1025 GA ++EGSAALMEKACOB SGZBD; ++EGSAALMEKACOBSDRAL Trade name: [REDACTED] - realloy Ga280 [REDACTED]	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1027 BCC ++EGSAALMEKACOB SGZBD; ++EGSAALMEKACOBSDRAL Trade name: [REDACTED] - realloy BC	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
- [REDACTED] GS-Alloy 1027 BCC Blank ++EGSAALMEKACOBSFB9S Trade name: [REDACTED] - realloy BC Blank	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1027 BCC Powder ++EGSAALMEKACOBSPUBW Trade name: [REDACTED] - realloy BC Powder	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1027 BCC Softblank ++EGSAALMEKACOBSSBAZ Trade name: [REDACTED] - realloy BC Softblank	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1027 BCC Softblank R ++EGSAALMEKACOBSSBAZ Trade name: [REDACTED]	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
[REDACTED] - realloy BC Softblank R GS-Alloy 1030 LA ++EGSAALMOGUCOBSGZST; ++EGSAALMOGUCOBSDRS2 Trade name: [REDACTED]	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
[REDACTED] GS-Alloy 1035 MG ++EGSAALMOGUCOBSGZST; ++EGSAALMOGUCOBSDRS2 Trade name: [REDACTED]	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
[REDACTED] - Modell FH GS-Alloy 1040 FH ++EGSAALMOGUCOBSGZST; ++EGSAALMOGUCOBSDRS2 Trade name: [REDACTED] [REDACTED] - Modell EH	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			
GS-Alloy 4080 LFC ++EGSAALMEKACOBGZBD; ++EGSAALMEKACOBSDRAL Trade name:  - realloy LFC	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1055 BMS ++EGSALOTCOBSK9 Trade name:  - realloy Universal Lot 	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 1056 Laserdraht ++EGSALASCOBSD8 Trade name:  - realloy Laserwire 	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
GS-Alloy 5010 N+ ++EGSAALMEKANIBSGUDG Trade name:  - realloy N+ - 	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 5010 N+ Blank ++EGSAALMEKANIBSFBC7 Trade name:  - realloy N+ Blank	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 5010 N+ Powder ++EGSAALMEKANIBSPUEB Trade name:  - realloy N+ Powder			
GS-Alloy 5011 Easy ++EGSAALMEKANIBSGUDG Trade name:  - 	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 5012 N ++EGSAALMEKANIBSGUDG Trade name:  - 	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
- realloy N			
GS-Alloy 5013 M11 ++EGSAALMEKANIBSGUDG Trade name: 	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578
GS-Alloy 5015 Base ++EGSAALGUFEBSGUSU Trade name: - realloy Base	Class IIa	N/A	93/42/EEC Annex V Certificate No.: 44235151578

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/01/05	Rev00	Initial issue
2024/02/06	Rev01	Adding trade names, according to P111F007_Produktliste_GSA_rev00
2024/05/07	Rev02	Adding trade names, according to P111F007_Produktliste_GSA_rev01
2025/03/17	Rev03	Adding trade names, according to P111-F-007 Produktliste GSA Rev.03 2025-03-13
2026/03/18	Rev04	Adding and deleting trade names, according to P111-F-007 Produktliste GSA 2025-10-30
2026/09/16	Rev05	Adding and deleting trade names, according to P111-F-007 Produktliste GSA 2026-08-17